Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data[1]

I. Purpose of Guidance

Sponsors frequently want to disseminate reprints of articles reporting the results of the effectiveness trials that have been relied on by FDA in its approval or clearance of a drug, device, or biologic product. However, such articles may contain effectiveness rates, data, analyses, uses, regimens, or other information that is different from the approved labeling, and might, if disseminated by the sponsor, be considered violative promotional activities.

Nonetheless, the agency intends to allow the dissemination of reprints of articles that represent the peer-reviewed, published version of original efficacy trials, under the circumstances described in section II. below.

II. Circumstances for Dissemination of Certain Journal Articles Discussing FDA-Approved Products

1. The principal subject of the article should be the use(s) or indication(s) that has been approved by FDA. The article should be published in accordance with the regular peer-review procedure of the journal in which it is published, and the article reports the original study that was represented by the sponsor, submitted to FDA, and accepted by the agency as one of the adequate and well controlled studies providing evidence of effectiveness. In the case of a medical device, this guidance also applies to studies that were otherwise represented by the sponsor, submitted to the agency, and accepted by the agency as valid and material evidence of safety or effectiveness in lieu of adequate and well controlled studies;

2. The reprint should be from a bona fide peer-reviewed journal. A bona fide peer-reviewed journal is a journal that utilizes experts to review and objectively select, reject, or provide comments about proposed articles. Such experts should have demonstrated expertise in the subject of the article under review, and be independent from the journal;

3. If the article contains effectiveness rates, data, analyses, uses, regimens, or other information that is different from approved labeling, the reprint should prominently state the difference(s), with specificity, on the face of the reprint. One acceptable means of achieving the appropriate prominence for this statement is to permanently affix to the reprint a sticker stating the differences; and

4. The reprint should disclose all material

[1]This guidance does not apply to reprints of articles that discuss the specific prohibited uses of animal drugs listed in the FDA, Center for Veterinary Medicine Compliance Policy Guide 7125.06 or the Animal Medicinal Drug Use Clarification Act implementing regulations. Although this guidance does not create or confer any rights on any person and does not operate to bind FDA in any way, it does represent the agency's current thinking on the dissemination of reprints of certain published, original data. The agency will consider individual circumstances on a case-by-case basis.

Guidance for Industry Funded Dissemination of Reference Texts[2]

I. Purpose of Guidance

Sponsors have also expressed a desire to disseminate reference texts, i.e., medical textbooks and compendia, to health care professionals. These texts typically discuss a wide range of medical diagnoses and treatments, including drug product utilization, surgical techniques, and other medical topics. FDA recognizes that such texts are often useful to clinicians in the practice of medicine.

Reference texts often contain information about the use of drugs, devices, or biologic products in the treatment, diagnosis, or prevention of disease that may not be consistent with the FDA-approved labeling for the products (e.g., discussion of unapproved uses). FDA recognizes, however, that many textbooks do not necessarily highlight a particular drug or device manufacturers products. In such instances, industry's desire to disseminate these reference texts may be in conflict with the Federal Food, Drug, and Cosmetic Act (the act) and implementing regulations.[3]

Nonetheless, FDA intends to permit the distribution of sound, authoritative materials that are written, published, and disseminated independent of the commercial interest of a sponsoring company and are not false nor misleading. FDA, therefore, intends to allow the dissemination by sponsors of reference texts that discuss human or animal drug, device, or biologic products, under the circumstances described in section II. below.

II. Circumstances for Dissemination of Reference Textbooks

1. The reference text should not have been written, edited, excerpted, or published specifically for, or at the request of, a drug, device, or biologic firm (see discussion below);

2. The content of the reference text should not have been reviewed, edited, or significantly influenced by a drug, device, or biologic firm, or agent thereof (see discussion below);

3. The reference text should not be distributed only or primarily through drug, device, or biologic firms (e.g., it should be other distribution channels where similar books are normally available);

4. The reference text should not focus primarily on any particular drug(s), device(s), or biologic(s) of the disseminating company, nor should it have a significant focus on unapproved uses of the drug(s), device(s), or biologic(s) marketed or under investigation by the firm supporting the dissemination of the text; and

5. Specific product information (other than the approved package insert) should not be physically appended to the reference text.

The agency recognizes that there are some useful reference texts that are written, edited, or published by a sponsor or agent of the sponsor. In these instances, FDA intends to allow the distribution of a reference text under the circumstances described in paragraphs 3 through 5 above, when the authorship, editing, and publishing of the reference text results in the presentation of a balanced perspective of the subject matter. Typically, this would be evidenced by an authorship and editorial process that fosters input from a relatively wide spectrum of sources and that allows for information from all sources to be considered.

[2]Although this guidance does not create or confer any rights, on any person, and does not operate to bind FDA in any way, it does represent the agency's current thinking on industry funded dissemination of reference texts. Although FDA believes that this guidance encompasses the vast majority of reference texts, the agency will consider, on a case-by-case basis, reference texts that do not fall within the parameters of this guidance document. This guidance does not apply to textbooks or compendia that discuss the specific prohibited uses or animal drugs listed in the Center for Veterinary Medicine Compliance Policy Guide 7125.06 or the Animal Medicinal Drug Use Clarification Act implementing regulations.

[3]Printed materials, such as medical textbooks and compendia, which supplement, explain, or are textually related to a regulated product are considered labeling for that product when disseminated by or on behalf of the manufacturer, packer, or distributor of the product. See section 201(m) of the act (21 U.S.C. 321(m)) and *Kordel* v. *United States*, 338 U.S. 345, 350 (1948).

Dated: November 30, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–29663 Filed 12–1–95; 1:21 pm]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel

Date: December 5, 1995.

Time: 3 p.m.

Place: Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Phyllis L. Zusman, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1340.

Committee Name: National Institute of Mental Health Special Emphasis Panel

Date: December 11, 1995.

Time: 1:30 p.m.

Place: Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Michael D. Hirsch, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1000.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: December 14, 1995.
Time: 1:30 p.m.
Place: Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.
Contact Person: Angela L. Redlingshafer, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1367.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: December 4, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–29874 Filed 12–4–95; 1:41 pm]

BILLING CODE 4140–01–M

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.
Name of SEP: Biological and Physiological Services.
Date: December 13, 1995.
Time: 12:30 p.m.
Place: NIH, Rockledge 2, Room 5198, Telephone Conference.
Contact Person: Dr. Peggy McCardle, Scientific Review Administrator, 6701 Rockledge Drive, Room 5198, Bethesda, Maryland 20892, (301) 435–1258.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

Name of SEP: Biological and Physiological Sciences.
Date: December 20, 1995.
Time: 1:00 p.m.
Place: NIH, Rockledge 2, Room 4142, Telephone Conference.
Contact Person: Dr. Edmund Copeland, Scientific Review Administrator, 6701 Rockledge Drive, Room 4142, Bethesda, Maryland 20892, (301) 435–1715.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 4, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–29873 Filed 12–5–95; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–066–96–1300–00; CACA–20139 and CACA–22901]

Proposed Sand and Gravel Mining Operation in Soledad Canyon, Los Angeles County, CA

AGENCY: Bureau of Land Management, Department of the Interior, Palm Springs-South Coast Resource Area, Desert District, California.

ACTION: Notice of Intent to prepare an Environmental Impact Statement—Second Notice.

SUMMARY: In compliance with the National Environmental Policy Act (NEPA) of 1969 and 40 CFR 1508.22, notice is hereby given that the Bureau of Land Management (BLM) will prepare an Environmental Impact Statement (EIS) for the Transit Mixed Concrete (TMC) Surface Mining Project (Project) proposed for construction and operation in Soledad Canyon, Los Angeles County, California. TMC acquired the rights to develop the Project through a competitive bid process. The BLM granted the mineral material contract to TMC in March 1990. The BLM complied with NEPA for the sale of sand and gravel for the Project site by preparing an Environmental Assessment (EA) and issuing a Finding of No Significant Impact (FONSI) in 1989.

The Project plans to mine a total of 83 million tons of materials and sell approximately 56 million tons of sand and gravel, also known as Portland cement concrete sand and gravel (PCC aggregates), over a 20-year period to fulfill contracts entered into with the BLM.

The Project includes plans to operate a concrete batch plant to produce and deliver ready-mixed concrete to the local market. All proposed mining and operations will be located north of Soledad Canyon Road and the Santa Clara River. The 500-acre site represents one of the westernmost reserves for PCC aggregate production in the Saugus-Newhall Production-Consumption Region that is located outside the floodplain of the Santa Clara River or a tributary wash.

The general mining plan is to mine on the south side of the ridge through a series of four excavation cuts. Each cut will progress from a higher elevation and proceed downslope. Fill areas for excess natural fines will be established on both the south and north sides of the ridge. Reclamation will be concurrent with mining operations and measures have been incorporated into Project design to minimize erosion, provide watershed control, and protect water quality in the Santa Clara River. A full range of alternatives to the proposed action will be considered in the EIS.

SUPPLEMENTARY INFORMATION: The Project site is on ''split-estate'' lands where the surface is privately owned and the minerals are federally owned and administered by the BLM. The project is subject to approval of a Surface Mining Permit and environmental analysis in accordance with the California Environmental Quality Act (CEQA). The County of Los Angeles is the Lead Agency for preparation of an Environmental Impact Report (EIR) which will be prepared separate from the EIS.

Comments from members of the public are being requested to help identify significant issues or concerns related to the proposed action to determine the scope of the issues and alternatives that need to be analyzed, and to identify and eliminate from detailed study the issues that are not significant. All comments recommending that the EIS address specific environmental issues should contain supporting documentation and rationale.

A Notice of Intent announcing BLM's intent to prepare an Environmental Impact Statement for the proposed project, was previously published in the Federal Register October 16, 1995. The public comment period closed November 15, 1995. Per public request,